REMARKS

Claims 1-55 are in the application.

Claims 2-22 and 29-55 were rejected under 35 USC 112, second paragraph, as being narrative and indefinite. The Examiner specifically noted that claims 2, 4, 29, 30 and 31 have specifically unclear and/or confusing language. As required, all the claims have accordingly been amended to clarify the language.

With respect to specific citations of lack of clarity, claim 2 has been amended to clarify the phrases "and has an outer diameter is enlarged with the tip end of the dilator" and "toward an apart side from a side in the vicinity of the tip".

In claim 4 (and claim 31) the apparent contradiction between "an enlarged portion" and "a large diameter portion enlarged" has been resolved with the above clarifying amendments. The enlarged diameter portion comprises two section components of a small diameter portion and a large diameter portion, the latter being "progressively increased" in a direction toward the tip.

Claims 29 and 30 have been clarified to specify that it is the trocar hold portion which bulges and reference to the dilator insertion portion is as a relative position relationship. Claim 30 has been amended to clarify the wording cited by the Examiner.

Claims 1-4, 14, 27 and 29 were rejected as being anticipated by Farrell. Claims 5-7, 10-12, 15-17, 19-21, 24-25, 30-34, 37-39, 41-44, 46-48, 51-52 and 54 were rejected under 35 USC 103(a) as being unpatentable over Farrell in view of Maaskamp. Claims 8, 13, 18, 22, 26, 28,35, 40, 45,49, 53 and 55 were rejected under 35 USC 103(a) as being unpatentable over Farrell in view of Maaskamp et al further in view of Kambin.

Farrell was cited as disclosing a trocar (sleeve) 24 with dilators 17, 18 and 19 and with puncturing probe 16 with puncturing tip 14. The Maaskamp reference was cited as showing a transitional conical section and ultrasonic application and Kambin was cited as showing an acute angle cut for the probe within the claims limitations in the needle shown therein.

In response to all the rejections based on the Farrell reference it is submitted that the Examiner has started from an erroneous reading and understanding of the teachings of Farrell. Farrell does not and cannot be read as disclosing a puncturing probe as required by all of the present claims.

With specific reference to the two independent claims 1 and 29, the trocar system in both claims comprises an elongated probe with a tip end configured for forming a puncture hole. The probe is inserted into a sheath, which probe and sheath are inserted into a dilator and then the probe, sheath and dilator are inserted into a trocar (claim 1 and claims dependent thereon). Claim 29 does not include a separate dilator and is adapted for smaller trocars. To emphasize that the presently claimed system is a device having a configuration which, in one insertion, forms a puncture hole, dilates the hole, and installs a trocar with removal of the puncture probe, sheath element and dilator element, the claims have been amended to positively claim that the probe has a tip end configured to form a puncture hole.

Both claims 1 and 29 have been amended to positively claim that the probe has a tip end configured to form a puncture hole.

To facilitate the initial puncture formation by the puncture probe of the system, claims 8, 13, 18, 22, 26, 28, 35, 40, 45, 49, 53 and 55 have been further amended to specify that the tip of the probe of normally conical shape is cut at an acute angle with a planar cut. In operation, the trocar system is a unit which forms a puncture hole, (with or without ultrasonic vibrations), dilates the hole until the trocar element is in place and then the probe, sheath and dilator (if present) are removed from the trocar as a unit.

In direct and clear contrast, Farrell's device is comprised of a series of non-puncturing dilators contained within a sheath, with all the dilators (including dilator 16 with tip 14-cited as being a puncturing element) being specifically configured to be used in a preformed needle puncture and guided by an already placed wire, initially threaded through the needle. Thus, despite the Examiner's assertion and pictoral explanation there is no puncture probe nor any element which is used for or can provide a puncture hole in Farrell, as required in the trocar system of the present claims.

Though the Examiner has considered element 14 of dilator 16 of Farrell to be a perforating tip end (with reference to Fig. 1A and 3 of Farrell), the Examiner's attention is drawn to wire 13 of Farrell which passes through tip 14 and dilator 16, and the discussion of the Farrell device operation at column 3, lines 39-68. Farrell specifically requires a separate needle to form a perforation hole, with a wire 13 being threaded through the needle. Afterwards the needle is removed from the puncture hole and wire

and tip 14 and dilator 16, is guided along the wire 13 into position within the pre-formed perforation.

As shown in Figure 3, alluded to by the Examiner, dilators 16, 17, 18, (19) and cannula 24 are threaded over the wire 13 for being guided into place. Tip 14 has a hole therein to allow threading of the wire 13 therethrough but is not in itself a puncturing tip. In addition, dilator 16 (with tip 14) among the dilator sleeves is also characterized as being flexible and formed from a suitable polymeric material (column 2, lines 63-64). Tip 14 is thus not even inherently a perforating tip. Flexible polymeric material is generally not appropriate for use in a puncturing probe especially with ultrasonic operation (claims 6-8, 11-13, 16-18, 20-21, 24-27, 33-35, 37-40, 43-45, 47-49, and 51-53) since, it may be susceptible to damage or breakage under vibration conditions and heat build up. Thus, structurally, the Farrell reference is adapted for use with a separate perforating needle and the insertion of a guide wire through the needle before the placement of dilators. With specific reference to the Farrell disclosure:

> ..."the **present invention**, in one aspect, accordingly provides such a system **comprising of a series of dilator sleeves** of gradually increasing internal and external diameters, which can be **progressively inserted over a wire that has been placed into the body within a needle by which an initial, small perforation is made.** The dilator sleeves have smoothly tapered tips such that the perforation can be gradually enlarged without risk of tearing of the tissue. The sleeves are flexible ..." (col. 1, lines 37-45-emphasis supplied)

The dilator sleeves, including dilator 16 with tip 14, of Farrell thus do not provide a puncture hole but are wire guided into place by a prior needle made hole. The sleeves are not even capable of puncturing with Farrell further describing the dilator components including dilator 16 and tip 14 as being of a polymeric material, normally not suitable for puncturing :

> ..."It should be noted that **the internal diameter of the dilator 16 closely corresponds to the external diameter of a guide wire 13** (see e.g. FIG. 3) so that leakage of blood between the wire and the dilator does not occur, at least to any appreciable extent. Similarly, each of the dilators is freely but not loosely slidable in relation to its adjacent dilator**. The dilator sleeves are formed from a suitable polymeric material.** (col. 2, lines 57-64-emphasis supplied)

Dilator 16, with tip 14, is also specifically described as being placed over guide wire 13, already installed in a previously perforated hole. The following describes the procedure in operation, which refutes the Examiner's interpretation of structure.

> "...Referring now to FIGS. 6 through 23, an application for the system described is illustrated. Here, a femoral-femoral bypass is being installed, for example, for cardiac support.
>
> In FIG. 6, syringe 10a is illustrated having mounted to it a needle 10. The needle is being pushed through the skin into the inferior vena cava 44.
>
> Next, as shown in FIG. 7b, wire 13 is threaded through needle 10 and up into the inferior vena cava toward the heart. The wire acts as a guide for installation **of the remaining equipment** as described below.
>
> FIG. 7a illustrates the **removal of the needle 10 over the wire 13 after the wire is in place**.
>
> In FIG. 8, a scalpel 5 is used adjacent the wire 13 to make a small incision in the skin so that the latter will not impede the movement of the dilator sleeves.
>
> In FIG. 9, the inner dilator sleeve 16 is threaded over the wire 13 and upwardly into the vein.... " (col. 3, lines 39-54-emphasis supplied)

Since Farrell does not disclose perforation with tip 14 of dilator 16 but rather with a syringe prior to placement of the dilators, there is no reason or purpose for providing an angled cut of the tip (in fact this might skew guiding of dilator along wire 13 during placement). There is also no reason to provide any ultrasonic device in connection with the dilators since the perforation was made prior to placement of the dilators and there is no need to facilitate perforation.

The Maaskamp et al. reference cited in combination with Farrell in rejecting claims 5-7, 10-12, 15-17, 19-21, 24-25, 30-34, 37-39, 41-44, 45-48, 51-52 and 54 as well as in further view of Kambin, Maaskamp was cited as showing a conical transition section in the Farrell device. However, with reference to Figure 3 of Farrell, the edge of element 26 is close to sheath 24 and requires not transition conical shape for any purpose.

Accordingly, the Examiner is respectfully requested to reconsider the application, allow the claims as amended and pass this case to issue.

Respectfully submitted,

THIS CORRESPONDENCE IS BEING SUBMITTED ELECTRONICALLY THROUGH THE UNITED STATES PATENT AND TRADEMARK OFFICE EFS FILING SYSTEM ON DRAFT.

MAX MOSKOWITZ
Registration No.: 30,576
OSTROLENK, FABER, GERB & SOFFEN, LLP
1180 Avenue of the Americas
New York, New York 10036-8403
Telephone: (212) 382-0700